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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/050,366	03/31/98	JOHANNSSON	G 0151/00211

EXAMINER	
MOEZIE,F	
ART UNIT	**PAPER NUMBER**
1653	20

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BURTON A AMERNICK
POLLOCK VANDE SANDE & PRIDDY
1990 M STREET NW
SUITE 800
WASHINGTON DC 20036-3425

DATE MAILED: 07/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

U.S. G.P.O. 1999 460-693

Office Action Summary	Application No. 09/050,366	Applicant(s) Jfohannsson et al
	Examiner F. T. Moezie	Group Art Unit 1653

☒ Responsive to communication(s) filed on *04/05/00 and 05/04/00*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *22-24 and 28* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *22-24 and 28* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

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--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

STATUS OF CLAIMS

Claims 22-24 and 28 (all — claims in this application) are pending prosecution in this Office action.

CONTINUED PROSECUTION APPLICATION

The request for Continued Prosecution Application (CPA), submitted 04 May 2000, paper no. 18, has been entered.

PRELIMINARY AMENDMENT

The Preliminary amendment filed 04 May 2000, paper no. 19, has been entered.

SPECIFICATION

The specification is not in compliance with the USPTO recommended format. The recommended format was presented in an earlier Office action mailed 18 March 1999, paper no. 9 The following additional changes are suggested:

1) The headings for the various sections would have to follow the above format. It is noted that applicant has entered the headings for some sections, however the earlier heading have not been canceled which may result in confusion at printing.

2) Part (g), Brief description of the Several Views of the Drawing(s) does not appear following the Brief Summary of the Invention. Note, the content of the description of the Figs 1-3 at page 12, along with a proper heading, would have to be transferred to its designated section as shown earlier.

3) References cited at pages 21-25 of the specification (48 references) are to be deleted from the specification. If applicant wishes to have the references considered by the Patent and Trademark Office, applicant would have to provide the Office with (a) Form PTO-1449, i.e., a separate listing of the references, and (b) a copy of each reference for consideration by the examiner.

It is also suggested that applicant review the entire specification and correct any discrepancies which may not be obvious at first glance.

REJECTION - 35 USC 112, FIRST AND SECOND PARAGRAPHS

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-24 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Tables 1-4 show the results of the applicants' study . Applicant admits the objectives for "the present study abdominal/visceral obesity" (specification, page 2, line 20) and is not concerned with insulin resistance. Moreover, it is concluded that "thus, the prevention and treatment of non-insulin dependent diabetes mellitus ***may be*** possible" (page 3, lines 11-13). There is no indication of the possession of the claimed subject matter. Clearly, applicant does not have

the possession of the claimed invention as of the time of filing of this application.

Claims 22-24 and 28 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The use of growth hormone or a functional equivalent thereof in ***"A method for treating a patient for insulin resistance, said patient having the Metabolic Syndrome"*** is not enabled by the instant specification. There is no guidance or enablement for the use of GH (proportions) and there is no protocol for the methods of *treating a patient having insulin resistance* as of the time of filing of the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-24 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 22, the terminology "decreasing insulin resistance---thereby decrease said insulin resistance" render the claim indefinite and unclear due to the double inclusion of - decreasing

insulin resistance. Additionally, the term " a functional derivative thereof " render the claims indefinite as to the claims metes and bounds.

In claim 22, the term "The Metabolic Syndrome" fails to find antecedent basis in the earlier part of the claim. Moreover, it is not clear as to ***what is encompassed by the term.***

Finally, the term "grown hormone" in claim 24 render the claim indefinite and incorrect.

REJECTION - 35 USC 102(b)/103(a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-24 and 28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sonksen in U.S. Patent No. 5,426, 096.

The reference teaches the **use of growth hormone** in a method for **treating diabetes in a diabetic patient**, wherein the disease is defined as set forth at col. 1, lines 38+. Because the claims are drawn to a method for treating a patient for insulin resistance using a GH, wherein insulin sensitivity is present resulting from the use of insulin in treating diabetes, the treatment of insulin sensitivity would be inherent and /or obvious in view of the prior art teachings.

N.M.

AMENDMENTS AND REMARKS

The response filed 05 April 2000, paper no. 15, has been entered.

Remarks that the claims **now** explicitly recite "increasing insulin sensitivity" (page 2, second paragraph) are not well taken. Applicant has failed to show the support for such insertion in the specification as filed. In fact, there is no showing for treating a diabetic patient in the specification. The specification at page 2, lines 20+, shows that "In the present study men --- with abdominal/visceral obesity were treated with recombinant human GH (rhGH)". And at page 3, lines 8-9, applicant concludes theat "Thus, the prevention and treatment of non-insulin dependent diabetes mellitus may be possible". See also Tables 1-4 at pages 17-20 for the related

data, wherein there is no showing for a method of treating diabetes, regardless of insulin dependencies. Hence, there is no basis for "This is a very specific group of patients" at page 2 of Remarks.

Remarks regarding the teachings of (Sonksen) '096 regarding the "present claims relate to the reverse action of GH, which is a new and unexpected finding --- ", paragraph bridging pages 3 and 4, are not convincing since the argument is based on speculation and there is no support for such assertions in the specification as filed.

Remarks regarding the traversal of the rejection of the claims under 35 USC 103 (a) over '096 are not persuasive. Because there is no enablement in the specification regarding the claimed subject matter (page 3, lines 11-13 of specification) the rejection is valid and maintained. The case laws cited by applicant are not effective since applicant has failed to point out any possible correlation between the instant claims and the claims in the cited decisions.

The Preliminary Amendment filed 04 May 2000, paper no. 19, has been entered.

Claims 19-21, 25-27 and 29-40 has been canceled. Claim 22 (the only independent claim in this application) has been amended. However, applicant has failed to clearly point out the basis for the amendment. See, MPEP Secs. 714.02 and 2163.06 (Applicant should specifically point out the support for any amendments made to the disclosure).

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CONCLUSION

No claims are allowed.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Mr. LOW (SPE) at 308-2923. FAX: (703) 305-4508.

F. T. Moezie

F. T. MOEZIE
PRIMARY EXAMINER
ART UNIT 1653